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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,515	07/27/2001	Garry Taylor	21663/0193	7055

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EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/915,515	TAYLOR ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-21* is/are pending in the application.

4a) Of the above claim(s) *11 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9,10,14,21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Response to election of species requirement filed 09/07/2004 is acknowledged. Applicant elected species of claim 10, drawn to inhibitor designed to form salts with arg416 and arg 498.

Claims 1-12,14-21 are pending. Claims 7,8,15-20 remain withdrawn from further consideration as being drawn to a non-elected group; applicant authorizes examiner to cancel these claims upon identifying allowable subject matter. Claims 11,12 are withdrawn from consideration as drawn to non-elected species.

Claims 1-6,9,10,14,21 are under examination.

Rejections not reiterated from previous Office actions are hereby withdrawn. The following rejections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-6,9,10,14,21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim

the subject matter which applicant regards as the invention. The rejection is made for the following reasons:

A. The specification provides no antecedent basis or description of structure coordinates as recited in claim 1, and therefore does not support the claims.

Response to arguments

Applicant argues that Fig.5 supports the language "structure coordinates". Examiner disagrees. Fig.5 presents crystallographic data collection statistics (see specification, p. 5, bottom) and is silent about structure coordinates of the residues recited in claim 1.

B. The meaning of term "identifying" in claim 4 is not clear. With the vague scope of "chemical entities or fragments" recited in the claim it is no clear what method steps are associated with "identifying", and it is not clear how "chemical entities or fragments" are "identified" of being capable of associating.

C. The meaning and the scope of the term "applying" introduced in claim 1(step a) is unclear. There are no particular steps associated with "applying". Note that claim 4 which is meant to explain "applying", is not drawn to use of coordinates of 3-D structure, but rather is drawn to identifying moieties capable of interacting with the entire enzyme in general.

D. In regard to the term "chemical entities or fragments" recited in claim 4, the scope of the term is not clear, and thus it is not clear how to "identify" (addressed in the previous paragraph) and to "assemble" these "chemical entities or fragments". For example, if a moiety is molecule of water, which, most likely, will be capable of "associating with enzyme", how it is supposed to be "assembled" into a molecule of a potential inhibitor?

Claim Rejections - 35 USC § 112, first paragraph (written description).

3. Claims 1-6,9,10,14,21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to method for identifying a potential inhibitor for a paramyxovirus Hemagglutinin-neuraminidase, comprising the step of using a three-dimensional structure of the paramyxovirus hemagglutinin-neuraminidase as defined by the structure coordinates comprising the amino acid residues 174, 175, 190, 192, 199, 234, 236, 237, 254, 256, 258, 262, 299, 302, 317, 363, 364, 369,401, 416, 466, 498 and 526 according to SEQ ID NO: 1, and further comprising the steps of applying the three-dimensional structure to design or select the potential inhibitor, and obtaining the potential inhibitor.

The specification does not describe coordinates of residues of SEQ ID No. 1 recited in the claim 1. Applicant refers to Fig.5 as supports the language "structure coordinates". However, Fig.5 merely presents statistical data (see specification, p. 5, bottom) and is silent about structure coordinates of the residues recited in claim 1.

The inventor must be able to describe the item to be patented with such clarity that the reader is assured that the inventor actually has possession and knowledge of the unique method that makes it worthy of patent protection. The reader can certainly appreciate the goal but establishing goals does not make a patent. As the Court of Appeals for the Federal Circuit stated in a case involving

similar issues, an inadequate patent description that merely identifies a plan to accomplish an intended result "is an attempt to preempt the future before it has arrived." *Fiers v. Revel,* 984 F.2d 1164, 1171 (Fed. Cir.1993). To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; *see also Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"). There is no demonstration in the specification that applicants identified any paramyxovirus Hemagglutinin-neuraminidase inhibitor using particular coordinates recited in the claims. Similarly to *In re Wilder*, 736 F.2d 1516 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 1209 (1985), the specification did "little more than outline goals applicants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."

Section 112, first paragraph, requires the patentee to "show that an invention is complete by disclosure of substantially detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the invention. Even if the inventors were reasonably certain that paramyxovirus Hemagglutinin-neuraminidase inhibitor can be identified using particular coordinates of a binding site, there is no showing in the application that they had knowledge of any particular coordinates. There is no showing of a single embodiment demonstrating identification of an inhibitor using method as claimed. The reader can certainly appreciate the goal but establishing goals does not make a patent. An

inadequate patent description that merely identifies a plan to accomplish an intended result "is an attempt to preempt the future before it has arrived." *Fiers v. Revel,* 984 F.2d 1164, 1171 (Fed. Cir.1993).

4. Further, claims 1-6,9,10,14,21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make the invention. The claims address steps of using and applying three-dimensional structure of paramyxovirus Hemagglutinin-neuraminidase; however the specification does not appear to disclose suitable algorithms or implementations for the said method steps.

In addition, claim 4 addresses steps of "identifying" and "assembling" chemical entities or fragments; however the specification does not appear to disclose suitable algorithms or implementations for the said method steps. Neither there is an explanation on how to relate language of claim 4 directed to identification of a chemical entity capable to "associate with enzyme" in general - water, for example, will satisfy this criteria - with "applying" particular three-dimensional coordinates recited in claim 1.

Claim Rejections - 35 USC § 112, first paragraph (enablement).

5. Claims 1-6,9,10,14,21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As stated in the preceding written description rejection (see paragraph #3 above), specification does not describe coordinates of residues of SEQ ID No. 1. As there is no information about said coordinates, an artisan would not be able to make and use the invention as claimed without the need for undue experimentation.

6. Further, as stated in previous Office action of 01/22/2004, even if claims 1-6,9,10,14,21 have been enabled for method for identifying a potential inhibitor for a Newcastle disease virus (NDV) paramyxovirus Hemagglutinin-neuraminidase, the claims would not been enabled for design of inhibitors for method for identifying a potential inhibitor for any other paramyxovirus Hemagglutinin-neuraminidase, because the residues recited in claim 1 are limited to SEQ ID No. 1 which is the sequence of hemagglutinin-neuraminidase from Newcastle disease virus. There are no residues or coordinates specified for hemagglutinin-neuraminidase from any other sources. Note that within paramyxoviridae family hemagglutinin-neuraminidase sequenced vary widely in the range of 25% to 75% between species (see specification, p. 10, lines 2,3).

Applicant's only argument is that "persons skilled in the art once aware of the present disclosure could practice the invention without undue experimentation" (p. 11 of the response of 05/24/2002). The argument is not deemed convincing because the residues and their coordinates will be different in hemagglutinin-neuraminidase from other sources, and thus identification of inhibitor by matching three-dimensional structure will require different coordinates.

Claim Rejections - 35 USC § 103.

7. Claims 1-6,9,10,14,21 are rejected under 35 U.S.C. 103(a) as obvious over WO 97/09345.

WO 97/09345 teaches method for crystallizing hemagglutinin-neuraminidase from paramyxovirus , Newcastle disease virus in particular. The crystals obtained have high x-ray diffraction resolution of 1.5-3.9 A. See claims 1,3,7,12,13. The hemagglutinin-neuraminidase thus obtained is at least 567 residues long, and thus it contains residues 174, 175, 190, 192, 199, 234, 236, 237, 254, 256, 258, 262, 299, 302, 317, 363, 364, 369,401, 416, 466, 498 and 526 , i.e.residues addressed in the instant claims.

The reference does not teach use of the coordinates of the crystallized paramyxovirus hemagglutinin-neuraminidase for identification of potential inhibitors. However, it would be *prima facie* obvious to one skilled in the art to be motivated to use three-dimensional structure of a protein that is crucial for pathological activity of an infectious virus to identify potential inhibitors. One would have reasonable expectation of success because use of crystal structure for identifying

active sites and then identifying potential inhibitors is well known in the art. See, for example reference to Babu et al in applicant's response of 05/24/2002, p. 11, first paragraph.

As for the use of coordinates of particular residues as recited in claims 110, it would be obvious to an artisan to identify residues of interest from three-dimensional structure determined from a crystallized protein.

Conclusion.

8. No claims are allowed

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

11/8/04
mlb